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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,346	06/28/2001	Wayne D. Comper	48643-015	2638

7590

09/09/2002

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EXAMINER

BROWN, STACY S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/09/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/893,346

Applicant(s)

COMPER, WAYNE D.

Examiner

Stacy S Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 June 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1648

### **DETAILED ACTION**

1. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648**.

2. Claims 1-21 are pending and examined. During a telephone conversation with Robert Price (attorney of record) on September 4, 2002, a restriction requirement was discussed regarding the proteins, enzymes and hormones of claim 7. However, upon further consideration the requirement is withdrawn.

### ***Specification***

3. The disclosure is objected to because of the following informalities:

Paragraph [01] contains a blank. The Office notes that the instant application is a continuation-in-part of Serial no. 09/415,217. There is no other domestic priority for which this application can claim priority to.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 and depending claims recite method steps that would lead one to determine whether or not an agent is therapeutically effective. The preamble of the claims

Art Unit: 1648

recites a method for treating a person. Clarification is requested regarding the purpose of the claim: treatment or analysis of an agent.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 16-17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Trevisan *et al*<sup>1</sup>. The claims are drawn to a method for treating a person with renal disease/complications comprising administration of an agent, assaying a body fluid sample for presence, absence or decreasing amount of a particular protein over time. The assay indicates whether or not the agent is therapeutically effective. The renal disease/complication can be selected from a host of commonly known conditions selected from claim 2. The treatment agents are lysosome-activating compounds such as ACE inhibitors (ramipril). The protein assayed for can be any protein from claim 7. Claims 16-17 are drawn to limitations wherein the assaying is by chromatography (HPLC).

Trevisan discloses the effect of low-dose ramipril on microalbuminuria in type-2 diabetic patients over a period of six months (abstract). Urinary albumin concentrations were measured by radioimmunoassay. Glycosylated hemoglobin concentrations were determined via HPLC (page 877, col. 2, last paragraph). Therefore, the claims are anticipated by Trevisan.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trevisan in view of Suzuki *et al*<sup>ii</sup>. The claims are drawn to a method for treating a person with renal disease/complications comprising administration of an agent, assaying a body fluid sample for presence, absence or decreasing amount of a particular protein over time. The assay indicates whether or not the agent is therapeutically effective. Albumin can be detected with specific albumin dyes. Early stage of a disease can be diagnosed when modified albumin is present in increasing amounts over time. (The teachings of Trevisan are summarized above.)

Trevisan is silent on:

- Detection of albumin with specific albumin dyes.
  - However, the detection of albumin with specific dyes is a common method of detecting albumin as evidenced by Jain *et al*<sup>iii</sup>. Jain says that dye-binding methods for measuring albumin are known. It would have been obvious to substitute of dye of Jain for the method of detecting albumin taught by Trevisan. One would have been motivated to use the dye for assaying albumin from Trevisan's method and had a reasonable expectation of success that the dye would work because Jain teaches that methods for measuring albumin with dyes are known.

➤ Detection of early stage disease by assaying for modified forms of albumin.

- However, Suzuki discloses that detection of urinary microalbumin indicates early stage nephropathy (col. 1, lines 50-52). It would have been obvious to detect early-stage renal disease with Trevisan's method because Trevisan also measures microalbumin. One would have been motivated to diagnose early-stage disease and had a reasonable expectation of success because with a known method of measuring microalbumin (as evidenced by Suzuki) and that it would work because Trevisan measures microalbumin.

Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Conclusion***

7. Claims 8-15 are free of the prior art.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361.

Art Unit: 1648

The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown  
September 6, 2002



HANYEL T. PARK, PH.D.  
PRIMARY EXAMINER

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<sup>i</sup> American Journal of Hypertension, Ltd., 1995; 8:876-883.

<sup>ii</sup> US Patent 5,246,835.

<sup>iii</sup> US Patent 4,330,296.